

REMARKS

Claims 1-14, 20, 21, and 26-28 are pending in this application. The specification has been amended merely to clarify that this application is a § 371 National Stage Application of PCT/US03/035427, filed November 4, 2003. Applicants note that the priority claim was previously set forth in the Application Data Sheet submitted with the filing of this application in compliance with 37 C.F.R. § 1.78(a)(2)(iii) within the time period set forth in 37 C.F.R. § 1.78(a)(2)(ii). No new matter has been added.

The Office has required restriction between the following two Groups:

- I. Claims 1-14 and 28, drawn to compounds of Formula (I); classified in various subclasses of classes 540, 544, 546, 548, 549, and 514; and
- II. Claims 20-21 and 26-27, drawn to methods of use of compounds of Formula (I), classified in various subclasses of classes 540, 544, 546, 548, 549, and 514.

The Office has further required an election of a single species, including an exact definition of each substituent on the base molecule.

Applicants hereby elect Group I, claims 1-14 and 28, with traverse. While not stated explicitly in the Restriction Requirement, Applicants note that Group I appears to encompass pharmaceutical compositions of claims 13, 14 and 28 in addition to the compounds of Formula (I). Applicants further elect the compound of Example 6.7, 1-propyl-1H-benzotriazole-5-carboxylic acid, with traverse (see page 50, lines 11-12). The substituents for the elected correspond to the following values: R<sup>1</sup> is n-propyl; and R<sup>2</sup>, R<sup>3</sup>, R<sup>4</sup>, and R<sup>5</sup> are each hydrogen. Claims 1, 4-8, 12-14, and 28 of Group I read on the elected species.

Applicants respectfully traverse the restriction requirement and request rejoinder of Groups I and II on the grounds that: (1) the Office has failed to use the correct legal standard for determining restriction for a § 371 application (unity of invention); and (2) the claims of the restricted Groups have unity invention such that restriction is improper.

As a threshold matter, the Office has failed to apply the correct legal standard for determining restriction of a § 371 application, such as the present application. As will be appreciated, "unity of invention (not restriction) practice is applicable in ... national stage applications submitted under 35 U.S.C. 371." M.P.E.P. § 1893.03(d). Unity of invention must

be determined under the provisions of the PCT in a national stage application filed under 35 U.S.C. § 371. *Caterpillar Tractor Co. v. Com'r Pat. & Trademarks*, 650 F. Supp. 218 (E.D. Va. 1986). The legal standard for determining unity of invention is set forth in Rule 13, which states, in part:

the requirement of unity of invention ... shall be fulfilled ... when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

P.C.T. Rule 13.2; M.P.E.P. § 1850. The presence of a special technical feature linking the claims thus defines the unity of invention standard.

Rather than applying the unity of invention standard, the Office has utilized restriction practice for applications filed under 35 U.S.C. § 111, setting forth reasons for patentable distinctiveness (see Restriction Requirement, page 4-5). The Office, therefore, has failed to provide adequate reasons why the claims lack unity of invention as required by M.P.E.P. § 1893.03(d) and 37 C.F.R. § 1.499. Applicants, therefore, respectfully assert that the restriction requirement is improper and request rejoinder of Groups I and II.

Further, Applicants respectfully request rejoinder on the grounds that the claims have unity of invention with each other. The claims recite compounds of Formula (I), pharmaceutical compositions thereof and methods of use thereof. As summarized above, unity of invention depends on the presence of a special technical feature linking the claims. The examples in Chapter 10 of the PCT International Search and Preliminary Examination Guidelines ("Guidelines") make it clear that a compound and a pharmaceutical composition thereof will have unity of invention with each other. An examination of Example 10.35 of the Guidelines is particularly illuminating. Example 10.35 concerns two claims as follows:

Claim 1: Compound A.

Claim 2: An insecticide composition comprising compound A and a carrier.

The comments to Example 10.35 state that example claims 1 and 2 share the special technical feature of a compound A and, thus, have unity of invention. The compounds of Formula (I) of

claims 1-12 and the pharmaceutical compositions of claims 13, 14, and 28 are directly analogous to the claims of Example 10.35 and, therefore, should share unity of invention with each other.

Further, claims directed to a product, such as the compounds of Formula (I) in Group I, and methods for the use of the product, such as those in Group II, are considered to be permissible combinations having unity of invention. Accordingly, M.P.E.P. § 1850 provides that:

The method for determining unity of invention under PCT Rule 13 shall be construed as permitting, in particular, the inclusion of any one of the following combinations of claims of different categories in the same international application:

(A) In addition to an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for a use of the said product...

M.P.E.P. § 1850.III.A. As the claims of the present application are similarly directed to products (Group I) and the use of those products in treatment (Group II), Applicants respectfully assert that the claims are permissible under PCT Rule 13. Accordingly, Applicants respectfully request withdrawal of the restriction requirement and rejoinder of Groups I and II.

Applicants also traverse the election of species requirement. As a preliminary matter, Applicants respectfully note that the Examiner has not specified whether the election of species requirement is provisional or non-provisional in nature. As will be appreciated, when a series of chemical compounds is defined in a claim using so-called "Markush practice" enumerating alternative elements, "[t]he fact that the alternatives of a Markush grouping can be differently classified shall not, taken alone, be considered to be justification for a finding of a lack of unity of invention." M.P.E.P. § 1850. Instead, unity of invention will be established if:

- (A) All alternatives have a common property or activity; and
- (B) (1) A common structure is present, i.e., a significant structural element is shared by all of the alternatives; or
- (B) (2) In cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

M.P.E.P. § 1850. Applicants note that the Office has failed to set forth any reason why each species of Formula (I) lacks a common property or activity or lacks a significant structural element with the other species of Formula (I), as required by M.P.E.P. § 1850. The Office instead proposes to engage in post-election review of the claims to determine which compounds should be examined together based on common classification and subclassification, but fails to set forth any reason why each species would lack unity of invention with every other species of Formula (I) as required by M.P.E.P. § 1893.03(d) (see Restriction Requirement, page 3). Accordingly, Applicants respectfully request that the election of species requirement be withdrawn.

Further, in the event that the Office intended this to be a provisional election of species requirement, Applicants note that this type of post-election regrouping of the claims contravenes the procedure for a provisional election of species as set forth in M.P.E.P. § 803.02. As M.P.E.P. § 803.02 explains in detail, if the elected species is found to be allowable, the examination of the Markush-type claim must be extended to the extent necessary to determine the patentability of the Markush-type claim. Rather than regrouping the claims into an arbitrary determined subset of the Markush-type claim, M.P.E.P. § 803.02 requires the Office to extend examination to the entire Markush-type claim or elected Group upon determination of allowability of the elected species.

In summary, it is clear that this restriction and election of species requirement has not been perfected as the Office has failed to utilize the correct legal standards. Further, for the ample reasons set forth in this response, Applicants respectfully assert that the restriction and election of species requirements are improper and request withdrawal of both requirements.

Early reconsideration and allowance of all pending claims is respectfully requested. The Examiner is urged to contact Applicants' representative at the number below if there are any questions regarding this application.

The Commissioner is hereby authorized to debit any fee due or credit any overpayment to Deposit Account No. 06-1050. Further, if not accompanied by an independent petition, this paper constitutes a Petition for an Extension of Time for an amount of time sufficient to extend

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the deadline and authorizes the Commissioner to debit the petition fee and any other fees or credits to Deposit Account No. 06-1050.

Respectfully submitted,



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